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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,430	04/08/2004	Charli Kruse	B1180/20026	7174
3000 7590 07/24/2007 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212			EXAMINER HAMA, JOANNE	
			ART UNIT 1632	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/820,430	Applicant(s) KRUSE, CHARLI	
	Examiner Joanne Hama, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 15-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant filed a response to the Non-Final Action of December 15, 2006 on May 15, 2007. No amendment to the claims has been filed. As such, Applicant's arguments will be considered in light of the amended claims, filed August 25, 2004.

As indicated in the Office Action of December 15, 2006, claims 15-47 are withdrawn.

Claims 1-14 are under consideration.

Drawings

Applicant's arguments, see page 2 of Applicant's response, filed May 15, 2007, with respect to the objection to the drawings have been fully considered and are persuasive. Applicant has submitted new Figures 4 and 5. The objection of the drawings has been withdrawn.

Information Disclosure Statement

Applicant's arguments, see page 3 of Applicant's response, filed May 15, 2007, with respect to the objection to the IDS have been fully considered and are persuasive. Applicant indicates that as the IDS has been amended by the Examiner and that the full citation of Kruse has been cited on PTO-892, as well. The objection to the IDS has been withdrawn.

Claim Objection

Applicant's arguments, see pages 4-5 of Applicant's response, filed May 15, 2007, with respect to the objection of claims 4 and 6 have been fully considered and are persuasive. Applicant indicates that according to MPEP 809.02(a), Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim, and that the MPEP passage would be illogical if claims generic to a species election had to be cancelled or amended to delete non-elected species within those generic claims. The objection of claims 4 and 6 has been withdrawn.

Withdrawn Rejection

35 U.S.C. § 102

Applicant's arguments, see pages 6-7 of Applicant's response, filed May 15, 2007, with respect to the rejections of claims 1-8, 13, 14 as being anticipated by Bachem et al., 1998, have been fully considered and are persuasive. Applicant indicates that the cells taught by Bachem et al. are different from those taught by the specification as PSCs taught by Bachem et al., grew from tissue blocks and did not have the unrestricted ability to divide. (See also specification, page 14, 1st and 3rd parag.). The rejection of claims 1-8, 13, 14 has been withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

rat and human isolated pluripotent adult stem cells obtained by mechanically and enzymatically breaking up acinar tissue from pancreas and culturing for several weeks in culture vessels, during which time differentiated cells are removed, wherein said pluripotent adult stem cells differentiate into nerve cells (expressing PGP 9.5 and NF), glial cells (expressing S100 and GFAP), muscle cells (expressing SMA), cartilage (expressing collagen type II), exocrine glandular cells (expressing amylase and trypsin), endocrine glandular cells (expressing insulin), and epidermal cells (expressing cytokeratin), following organoid body formation,

does not reasonably provide enablement for

isolated pluripotent adult stem cells from any species of vertebrate obtained from any exocrine gland tissue, wherein said pluripotent adult stem cells differentiate into any cell type, for reasons of record, December 15, 2006.

Applicant indicates that the claimed invention is enabled for obtaining pluripotent adult stem cells from a variety of cell types from a variety of different organism and provides a declaration by Dr. Kruse (Applicant's response, page 4-5). In response, this

is not persuasive. Dr. Kruse indicates in the declaration that a number of tissues from a variety of animals were used to obtain isolated pluripotent adult stem cells (IPAS), and that a number of cell lines were established from the tissues, Table 1. While the declaration asserts that the cells obtained in Table 1 were IPAS cells, the declaration does not indicate that the cells were the same as those described in the specification, i.e., that they are able to differentiate into nerve cells (expressing PGP 9.5 and NF), glial cells (expressing S100 and GFAP), muscle cells (expressing SMA), cartilage (expressing collagen type II), exocrine glandular cells (expressing amylase and trypsin), endocrine glandular cells (expressing insulin), and epidermal cells (expressing cytokeratin), following organoid body formation. As indicated in the art, Henningson et al., 2003 and Zuk et al., 2002 teach that when stem cells are obtained from different tissues, they do not necessarily have the same differentiation potential (Office Action, December 15, 2006, page 6). The declaration indicates that IPAS cells isolated from human sweat glands express the stem cell marker nestin (declaration, page 4, point 7). According to the art, nestin is a neuronal stem cell marker (see Li et al., 2003, Nature Medicine, 9: 1293-1299, legend for Figure 2c) and expression of this marker is not indicative that the cell isolated from human sweat glands is able to differentiate into muscle and exocrine cells, as described in the specification. In addition to this issue, while the declaration indicates that cell lines were made from various species of animals (Table 1), the declaration does not indicate that these cells were the same (i.e. have the same differentiation ability) as those described in the specification. As such, the rejections as they apply to these issues remain.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 remain rejected under 35 U.S.C. 102(b) as being anticipated by Schneider et al., 2001, Am. J. Physiology, Cell. Physiol., 281: C532-543, see IDS, previously cited, as evidenced by Kruse et al., 2004, Appl. Phys. A, 79: 1617-1624, see IDS, previously cited, for reasons of record, December 15, 2006.

Claims 1-14 remain rejected under 35 U.S.C. 102(b) as being anticipated by Apte et al., 1998, Gut, 43: 128-133, see IDS, previously cited, as evidenced by Kruse et al., 2004, Appl. Phys. A, 79: 1617-1624, see IDS, previously cited, for reasons of record, December 15, 2006.

Applicant's arguments filed May 15, 2007 have been fully considered but they are not persuasive.

Applicant indicates that according to the Office Action, each of the cited documents, Schneider et al., Apte et al. and Bachem et al., anticipates the claimed subject matter, because the "pancreatic stellate-like cells" (PSLCs) described in Kruse et al., 2004, Discussion section, first paragraph, are said to "correspond" to the "pancreatic stellate cells" (PSCs) disclosed in said references. However, "correspond" merely indicates that both cell types exhibit similar morphological characteristics but

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does not acknowledge or suggest that both cell types are identical. Specifically, with respect to the cells described by Bachem et al., at least one important difference, namely a lack of the capability for unlimited division and stable proliferation, has been explicitly identified by Kruse et al. Therefore, the term "correspond", which also has been used by Kruse with respect to the cells of Bachem et al., cannot be construed as meaning "identical" (Applicant's emphasis, Applicant's response, page 5). In response, Applicant's arguments are persuasive with regard to Bachem et al., and the rejection as it applies to Bachem et al. is withdrawn.

With regard to Applicant indicating that the cells of Schneider et al. and Apte et al. are different from that of the claimed invention because they involve a step of density gradient centrifugation, and that the centrifugation step removes either the actual progenitor stem cells or important factors or helper cells which might be required to induce the proliferation or generation of stem cells (Applicant's response, page 6, 1st parag.), the argument is not persuasive. As far as can be told, the cell cultures taught by Schneider et al. and Apte et al. contain isolated pluripotent adult stem cells obtained from the pancreas. While Applicant indicates that it is conceivable that centrifugation removes progenitor cells, the Examiner believes that the cultures of Schneider et al. and Apte et al. contain stem cells because the cells could be plated. According to the specification, stem cells attach to the plate, while differentiated cells do not (specification, page 23, lines 20-22).

Applicant indicates that the present method for isolation of primary exocrine cells is very gentle and does not involve any centrifugation steps (Applicant's response, page

6, 2nd parag.). In response, this is not persuasive because centrifugation is used to obtain the claimed cells (see specification, page 21, line 6; page 23, line 2).

Applicant indicates that claim 1 is drawn to isolated pluripotent stem cells and that the stem cells are obtained by multiple cultivation steps and passages in the course of which the differentiated cells are gradually removed and only the pluripotent cells remain (Applicant's emphasis, Applicant's response, page 6, 3rd parag.). In response, this is not persuasive as the term, "isolated," is not so limited to a dish that exclusively contains stem cells and nothing in the specification indicates that "isolated" is limited to the specific scope, as indicated by Applicant. Rather, the term can be used to indicate that the cell was obtained from an animal. Because of this interpretation, the cultures taught by Schneider et al. and Apte et al. anticipate the claimed invention.

Thus, the claims remain rejected.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service

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Joanne Hama
Art Unit 1632

/Anne Marie S. Wehbe/
Primary Examiner, A.U. 1633